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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/572,341	03/17/2006	B. Wesley Trotter	21357YP	1346				
210 MERCK P O BOX 2000 RAHWAY, NJ 07065-0907	7590 05/12/2010		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">TRUONG, TAMTHOM NGO</td></tr></table>		EXAMINER		TRUONG, TAMTHOM NGO	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,341	<b>Applicant(s)</b> TROTTER ET AL.	
	<b>Examiner</b> TAMTHOM N. TRUONG	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-17 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) 6-17 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **FINAL ACTION**

Applicant's amendment of 2-19-10 has been fully considered. Although rejected claims have been cancelled, new claims still present the same indefiniteness issue, namely, the bond represented by variable "z". New claims are still anticipated by all previous references despite the new proviso. Also, the new proviso raises new ground of 112 rejection.

Claims 1-5, 18 and 19 are now cancelled.

Claims 6-17 and 20-22 are withdrawn.

Claims 23 and 24 have been added, and are the only pending claims.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 23 still recites "z" representing a "single or double bond". If "z" had been a single bond, then the ring carbon would have had an incomplete valence. If "z" had been a double bond, then the ring nitrogen would have had one bond too many, and there should have been a (+) charge on the ring nitrogen.

b. Also, if “z” had been a double bond, and R<sup>5</sup> had been a (=O) (or an oxo group), then the ring carbon would have had one bond too many.

c. The few compounds recited at the end of claim 23 raise the indefinite issue of “broad/narrow range”.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 23 and 24 recite the broad recitation of the quinazolinone genus, and the claim also recites species of said genus which is the narrower statement of the range/limitation.

Thus, it is not clear which set of compounds is intended.

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***Claim Rejections - 35 USC § 102***

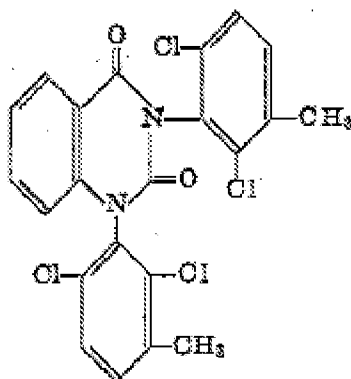
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

a. **Juby** (US 3,294,813): In column 10, Juby discloses the compound of *1,3-bis(2,6-dichloro-3-methylphenyl)-2,4-quinazolinone* with the following structure:



Said compound reads on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with halogens and an alkyl group;
- ii.  $R^1$  is  $(CR^aR^b)_nR^{40}$ ;  $n = 0$ ;

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- iii.  $R^{40}$  is an aryl group substituted with halogens and an alkyl group;
- iv.  $R^5$  is an =O group;
- v.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

b. **Lowe, III** (US 4,797,403): In column 8, Lowe discloses Example 14 with the compound of *1-(3-Carboxyphenyl)-3-benzylquinazoline-1H,3H-2,4-dione*, and also in column 9, Example 15 with the compound of *1-(3-N-Methylcarboxamidophenyl)-3-benzylquinazoline-1H,3H-2,4-dione*. Both compounds read on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with  $(CR^iR^j)_rC(O)OR^{46}$  wherein  $R^{46}$  is hydrogen, or the phenyl ring is substituted with  $(CR^iR^j)_rC(O)N(R^{47}R^{48})$  wherein  $R^{47}$  is hydrogen, and  $R^{48}$  is a methyl group;
- ii.  $R^1$  is  $(CR^aR^b)_nR^{40}$ ;  $n = 1$ ;
- iii.  $R^{40}$  is an aryl group;
- iv.  $R^5$  is an =O group;
- v.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

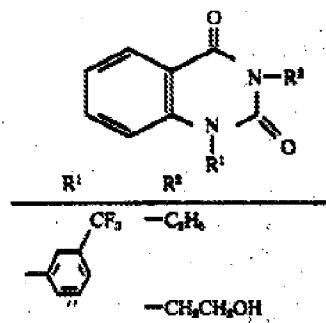
c. **Connor et. al.** (US 5,155,110): In column 30, Connor discloses Example 45 with the compound *1-(2,6-Dichloro-3-methylphenyl)-3-methoxy-2,4-(1H,3H)quinazolinedione*. Said compound reads on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with halogens and an alkyl group;
- ii.  $R^1$  is  $(CR^aR^b)_nOR^{40}$ ;  $n = 0$ ;

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- iii.  $R^{40}$  is an alkyl group;
- iv.  $R^5$  is an =O group;
- v.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

d. **Noda et. al.** (US 4,016,166): In columns 9 and 10, the compound having the following structure:



reads on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with  $(CR^iR^j)_rR^{46}$ ;  $r = 1$ ;
- ii.  $R^i$ ,  $R^j$  and  $R^{46}$  are fluoro;
- iii.  $R^1$  is  $(CR^aR^b)_nR^{40}$ ;  $n = 1$ ;
- iv.  $R^{40}$  is hydrogen or an alkyl group;
- v.  $R^5$  is an =O group;
- vi.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

e. **Yabuuchi et. al.** (DE 2,120,663 – cited on the IDS): On page 2, Yabuuchi et. al. discloses the compound of *1-(3'-Fluophenyl)-2,4(1H, 3H)-chinazolidion* which reads on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with a halogen (i.e., fluoro);

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- ii.  $R^1$  is hydrogen;
- iii.  $R^5$  is an =O group;
- iv.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

f. **Ozaki et. al.** (CAS printout XP-002520057 – cited on the IDS): The compounds of *Benzamide, 2-(2-methyl-4-oxo-1(4H)-quinazolinyl)* and *Benzamide, 2-(2-(1-methylethyl)-4-oxo-1(4H)-quinazolinyl)* read on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with  $(CR^iR^j)_rC(O)N(R^{47}R^{48})$ ;
- ii.  $r = 0$ ;  $R^{47}$  and  $R^{48}$  are hydrogen;
- iii. z is a double bond, and  $R^1$  does not exist;
- iv.  $R^5$  is a  $C_{1-6}$ alkyl group;
- v.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

g. **Moore et. al.** (CAS printout XP-002520060 – cited on the IDS): The compounds of *2,4(1H,3H)-Quinazolinedione, 1-(2-benzoylphenyl)* and *2,4(1H,3H)-Quinazolinedione, 1-(2-benzoylphenyl)-3-methyl* read on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with  $(CR^iR^j)_rC(O)R^{46}$ ;
- ii.  $r = 0$ ;  $R^{46}$  is an aryl group;
- iii.  $R^1$  is hydrogen or an alkyl group;
- iv.  $R^5$  is an oxo group;
- v.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.



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h. **Noda et. al.** (CAS printout XP-002520055 -- cited on the IDS): For example, the compound of *4(1H)-Quinazolinone, 7-chloro-2-methyl-1-(3-chlorophenyl)* reads on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with a halogen (chloro);
- ii.  $R^1$  does not exist because z is a double bond;
- iii.  $R^5$  is an alkyl group;
- iv.  $R^8$  is a halogen;
- v.  $R^2$  and  $R^9$ - $R^{10}$  are hydrogen.

i. **Ozaki et. al.** (J. Med. Chem., 1985, 28, pp. 568-576 – cited on the IDS): For example, compound #21 reads on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with a halogen (fluoro);
- ii.  $R^1$  does not exist because z is a double bond;
- iii.  $R^5$  is an alkyl group;
- iv.  $R^2$  and  $R^8$ - $R^{10}$  are hydrogen.

j. **Hisamitsu Pharm. Co.** (GB 1,311,573 – cited on the IDS): For example, on page 2, left column, lines 12-13, the compound of *1-(3'-chlorophenyl)-2,4-(1H, 3H)-quinazolinedione*, and lines 20-21, and the compound of *1-(3'-fluorophenyl)-2,4-(1H, 3H)-quinazolinedione* read on the instant quinazolinone formula with the following substituents:

- i. A is a phenyl ring substituted with a halogen (chloro or fluoro);

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- ii.  $R^1$  is hydrogen and z is a single bond;
- iii.  $R^5$  is an oxo group;
- iv.  $R^2$  and  $R^8-R^{10}$  are hydrogen.

See also other compounds in all the cited references.

### *Specification*

3. The abstract of the disclosure is objected to because of the following reasons:
  - a. When “z” is a single bond, then the ring carbon at 2-position has an incomplete valence.
  - b. When “z” is a double bond, and  $R^1$  is absent, and if  $R^5$  is =O, then the ring carbon at the 2-position has an extra valence.

Correction is required. See MPEP § 608.01(b).

Applicant's amendment **necessitated** the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAMTHOM N. TRUONG whose telephone number is (571)272-0676. The examiner can normally be reached on Monday thru Friday (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tamthom N. Truong/  
Examiner, Art Unit 1624

/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624

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5-06-10